



FW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Letts et al**

Application No: **10/718,060**

Group Art Unit: **1626**

Filed: **June 10, 2003**

Examiner: **Rebecca L. Anderson**

For: **Nitrosated and/or Nitrosylated Cyclooxygenase-2 Inhibitors, Compositions and Methods of Uses**

Attorney Docket No: **102258.157 US1**

Commissioner of Patents
PO Box 1450
Alexandria, VA 22313-1450

**Provisional Response to Restriction Requirement and
Request for Reconsideration of Restriction Requirement Under 37 C.F.R. § 1.143**

I. Introductory Comments

This response is submitted in reply to the Restriction Requirement dated June 14, 2005, for which a response is due on or before July 14, 2005.

No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the present application.

II. Request for Reconsideration of Restriction Requirement

Under 37 C.F.R. §1.143, Applicants respectfully request reconsideration of the restriction requirement dated June 14, 2005.

The examiner restricted the invention as follows:

| | | |
|-----------|-------------------|--|
| Group I | Claims 1-2, 53-55 | Compounds and compositions of Formula I |
| Group II | Claims 3-13 | Methods of use for the compounds of Formula (I) |
| Group III | Claims 14, 15 | Compositions of Formula I in combination with therapeutic agents |

Provisional Response to Restriction Requirement**Application No. 10/718,060****Page 2 of 5**

| | | |
|------------|----------------------------------|--|
| Group IV | Claims 16-26 | Methods of use for compositions of Group III |
| Group V | Claims 27-37, 57-66 ¹ | Compositions of Formula I in combination with nitric oxide donor compounds |
| Group VI | Claims 38-48, 70-79 ² | Methods of use for compositions of Group V |
| Group VII | Claims 49, 56 | Kits for the compounds of Formulas I |
| Group VIII | Claims 50, 51, 52 | Kits for the compounds of Formulas I in combination with NO donor compounds |
| Group IX | Claims 52 ³ | Kits for the compounds of Formulas I in combination with therapeutic agents |
| Group X | Claims 67, 68 ¹ | Compositions of Formula I in combination with nitric oxide donor compounds and/or therapeutic agents |
| Group XI | Claims 69-79 ¹ | Methods of use for compositions of Group X |
| Group XII | Claims 80, 81 ¹ | Kits for the parent compounds of Formulas I in combination with NO donor compounds and/or therapeutic agents |

The claims in the pending application are directed to:

- (i) compounds and compositions comprising **nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds of Formula (I)**, kits comprising the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds, and the methods of use for the compounds and/or compositions; and
- (ii) compounds and compositions comprising **the parent cyclooxygenase-2 inhibitor compounds of Formula (I)**, kits comprising the parent cyclooxygenase-2 inhibitor compounds, and the methods of use for the compounds and/or compositions.

¹ Applicant's would like to bring to the Examiner's attention that these claims 57-66, 67, 68, 69-79, 80 and 81 are drawn to the parent COX-2 inhibitors of Formulas (I) i.e. a COX-2 inhibitor compound that is not nitrosated and/or nitrosylated. The parent COX-2 inhibitors would include all the limitations of the compounds of Formulas (I) of claim 1 except that the variable Q must be a hydrogen atom.

² Applicant's assume this is typographical error as claims 69-79 have been assigned to Group XI

III. Restriction is Not Proper When the Claims are Related

As stated in MPEP §808.02, “[w]here, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U. S. C. §121 is never proper (MPEP §806.05).”

All the pending claims are related. Thus, the restriction requirement is not proper. To show that the inventions are distinct, the Examiner must show either that (1) there is a separate classification of the claims; (2) a separate status in the art when they are classifiable together; or (3) a different field of search. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

None of these three criteria have been shown with the claims of this application:

If the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions are allowable, then all the kits and methods of use for these compositions would also be allowable. In other words, every pending claim that requires a **nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compound** would also be allowable. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

A search of the prior art for the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds of Formula (I) and compositions would necessarily encompass a search of the prior art for their methods of use and the kits comprising the compounds. Thus, the prior art for the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds of Formula (I) and compositions of Groups I, III and V (in part) respectively, will also be the same prior art for their methods of use and kits for the compositions comprising the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds (i.e., Groups II, IV, VI, VII, VIII, IX).

If the parent cyclooxygenase-2 inhibitor compounds and compositions are allowable, then all the kits and methods of use for these compositions would also be allowable. In other words, every pending claim that requires a **parent cyclooxygenase-2 inhibitor compound** of Formula (I) would also be allowable. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

A search of the prior art for the parent cyclooxygenase-2 inhibitor compounds and compositions would necessarily encompass a search of the prior art for their methods of use and the kits comprising the compounds. Thus, the prior art for the parent cyclooxygenase-2 inhibitor compounds and compositions of Groups V (in part) and X of Formulas I respectively, will also

³ Applicant's assume this is typographical error and that the Examiner meant to refer to claim 53

be the same prior art for their methods of use and kits for the compositions comprising the parent cyclooxygenase-2 inhibitor compounds (i.e., Groups XI, XII).

III. Proposed restriction requirement

Applicants respectfully propose the following restriction requirement:

| | | |
|----------|--------------|--|
| Group I | Claims 1-56 | Compounds, compositions, kits and methods of use for nitrosated and/or nitrosylated COX-2 inhibitor of Formula I |
| Group II | Claims 57-81 | Compounds, compositions, kits and methods of use for <u>parent</u> COX-2 inhibitor of Formula I |

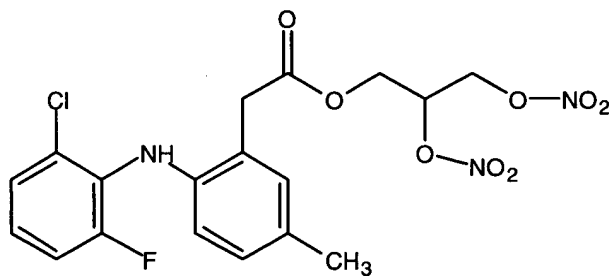
IV. Provisional Response to Restriction Requirement

Applicants provisionally elect Group I, claims 1-2, 53-55 drawn to the nitrosated and/or nitrosylated compounds and compositions of Formula I, with traverse.

V. Election of Species

In response to the election of species requirement, Applicants elect the nitrosated cyclooxygenase inhibitor compound of Formula V, 2,3-bis(nitroxy)propyl 2((2-chloro-6-fluorophenyl)amino)5-methylphenyl)acetate, with traverse.

This compound has the structure:



(V)

The compound is disclosed in the specification at page 23, line 15 to page 24, line 3.

Provisional Response to Restriction Requirement

Application No. 10/718,060

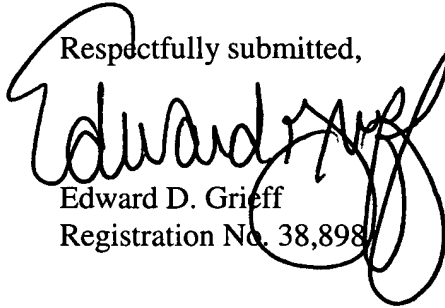
Page 5 of 5

VI. Conclusion

Applicants respectfully request that the restriction requirement be withdrawn and be replaced with Applicant's proposed restriction requirement.

An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Edward D. Grieff", written over the typed name and registration number.

Edward D. Grieff
Registration No. 38,898

Date: July 8, 2005

WILMER CUTLER PICKERING

HALE AND DORR LLP

1455 Pennsylvania Avenue, NW

Washington, DC 20004

Phone: (202) 942-8453